## PCT

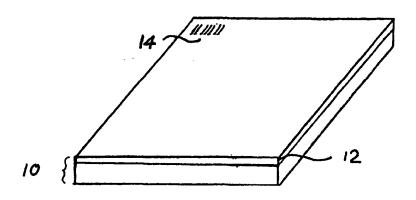
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(54) Title: A METHOD OF INDIVIDUALLY TRACKING AND IDENTIFYING A DRUG DELIVERY DEVICE



### (57) Abstract

A method of and system for identifying an individual drug delivery device and tracing its ownership. An individual drug delivery device, such as a patch, is coded with a unique identifier. Such coding is performed by using a bar code or by storing the identifier in a memory device in the drug delivery device. A database contains a record of the identifier, representing the drug delivery device. The identifier is read upon a transfer of the drug delivery device and the database is updated to include information such as the date of the transfer, the identity of the transferee and the prescribing physician. The ability to retrieve such information regarding specific drug delivery devices can result in the prevention of abuse of controlled substances contained therein.

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# A METHOD OF INDIVIDUALLY TRACKING AND IDENTIFYING A DRUG DELIVERY DEVICE

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### Background of the Invention

The invention relates generally to drug delivery devices. Specifically, the present invention relates to the tracking and identification of an individual prescription drug delivery device, such as an adhesive patch, and involves encoding the drug delivery device with pertinent information.

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While there is no limitation on the type of drug that can be used with the present invention, invention has particular applicability for "controlled substances" such as those listed in the regulations promulgated pursuant to the Food, Drug and cosmetic Act, 21 C.F.R. §§ 1308 et seq., and include substances having a stimulant or depressant effect on the central nervous Because stimulant drugs have a high potential system. for abuse, the U.S. Drug Enforcement Administration stringent controls their has placed (DEA) and manufacture, distribution prescription. example, the DEA requires special licenses for these activities.

One such prescription stimulant drug is methylphenidate (MPH). MPH, manufactured and sold by Novartis Pharmaceuticals Corporation (formerly Ciba-Geigy) under the brand name Ritalin, is used in the treatment of attention deficit and/or hyperactivity disorders in both children and adults. Experts estimate that such disorders affect 3.5 million children and 17

million adults -- and perhaps even as much as 10 percent of the American population. MPH helps individuals suffering from such disorders stay calm and focused, and often improves their behavior, grades and even their About 1.5 million school-age youngsters self esteem. have been prescribed MPH in mid-1995, with more recent estimates climbing to about 2.4 million.

However, use for illicit, non-medicinal purposes increasingly reported particularly being college and high school students. In 1994, a national high school survey (Monitoring the Future) indicated that non-prescription use of MPH doubled among high school seniors between 1993 and 1994, resulting in more seniors abusing MPH than are actually prescribed it 15 legitimately. Similar to cocaine or amphetamines in the nature and duration of their effects, abusers are crushing Ritalin tablets into powder which they then snort to get a quick high.

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Diversion or abuse of MPH is not however limited Diverse segments of the population from health care professions to street addicts have also been implicated. Organized drug trafficking groups are using various schemes to obtain MPH for resale on the illicit market. According to the DEA, MPH ranks among the most frequently reported controlled pharmaceuticals stolen from licensed handlers.

Law enforcement and other authorities confiscate 30 specifically, controlled prescription and drugs from unauthorized users or unlicensed substances, It would be useful, to be able to identify handlers. the specific product, such as the individual drug delivery device, and be able to trace the origin of that 35 specific product to determine the identity of the last the product, licensed handler of the prescribing

physician, pharmacy or patient, etc. Currently, there is no way to identify the ownership or trace the origin of a prescription drug once it is removed from the prescription packaging.

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Presumably, if a legitimate handler believes that the individual prescription drugs it dispenses can be traced back to him or her, the handler will be less inclined to distribute the drug illegally and will take greater precautions against loss or theft. The criminal penalties for illegal distribution and use of controlled substances are severe. Thus, providing authorities with a system for accurately identifying the last known legitimate handler of or other pertinent information regarding a particular prescription drug product would help to reduce the potential for abuse and illegal distribution of the product. It would also make available more of the supply of the drug for use by legitimate users with a medical need.

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Placing the drug in a delivery system that can control the release rate of the drug in the body or to a site of application, such as an adhesive patch, can help to reduce the potential for abuse of the drug over other conventional dosage administration forms. Nevertheless, the potential for abuse and misuse still exists even with the use of such patches.

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## Summary of the Invention

Having recognized the above described problem and need, the inventors have developed the following solution, which is embodied in the present invention. The invention is a system for identifying an individual drug delivery device and tracing its ownership. It will be apparent to one skilled in the art that the invention

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has applicability with a variety of drug delivery devices, forms and drugs.

In one embodiment of the invention, an individual is encoded with drug delivery device а soon usually during after identifier, orIn addition to reducing the potential for manufacture. abuse of the drug through insufflation or injection, the use of a drug delivery device such as an adhesive patch facilitates such coding of individual products. identifier may be a visible marking such as alphanumeric string or a bar code and is indelibly printed onto the drug delivery device. In the case of a patch, the visible identifier may be printed onto the backing of the patch. Such an identifier may be recognizable by a human or by an electronic and/or optical device, such as a scanner.

Once the unique identifier has been placed on or in the drug delivery device, a corresponding identifier is created in a database. Information corresponding to each drug delivery device is added to the database as the devices are distributed. Αt each level distribution, the individual device identifiers can be scanned, causing relevant information, such as the name of the handler and the date, to be transmitted and appended to the database at a location corresponding to Usually, more than one drug the device identifier. delivery device is transferred between handlers; accordingly, the packaging of the devices, such as a box, will contain a separate identifier corresponding to the devices contained therein. In those cases, the box identifier is scanned causing the data corresponding to multiple device identifiers in the database to be updated with the same handler information. Ultimately, when a drug prescription is filled by the last handler, the individual devices given to the user are scanned causing the database to be updated with information regarding the end-user to whom the individual device was dispensed. Database updates can be performed immediately upon scanning or at some later time.

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Under the present invention, authorities have the ability to accurately identify and trace the ownership of any of the drug delivery devices found or confiscated from an unauthorized user. Using the unique identifier on or in an individual drug delivery device, authorities can access the database and obtain information regarding the device such as the identities of: the person to whom the drug was dispensed, the pharmacy or other handler that dispensed the drug and any preceding handlers, such as distributors, of the device. Also, the obtained information can include the date when the device came into the possession of each of the handling parties listed.

- Using this information, authorities are better able 20 to investigate and reduce the occurrence of illegal distribution or theft of the drug delivery devices, which, as discussed, can contain controlled substances knowledge that such In addition, such as MPH. information is available to authorities will serve to 25 inclination a handler may diminish any distribute the drug illegally. It will also encourage all handlers to take greater precautions against loss or Furthermore, the theft or the drug delivery devices. reduction of abuse and illegal distribution of the 30 controlled substance contained in the drug delivery device will make available more of the supply of the drug for use by legitimate users with a medical need.
- In an alternative embodiment of the present invention, the drug delivery device comprises a memory device such as a microchip or Radio Frequency

Identification (RFID) tag instead of visible markings. In a patch, the microchip or RFID tag can be disposed on or in the backing layer of the patch. The memory device serves to uniquely identify the drug delivery device.

All pertinent information regarding the delivery device, the identities of the handlers and the legitimate user as well as the prescribing physician, can be stored in the microchip or RFID tag itself. Upon recovery of such a drug delivery device, authorities can, with the assistance of a microchip or RFID reader, extract the information from the microchip or RFID tag contained in the delivery device. A database may be used to provide additional information regarding the specific drug delivery devices, or in the situation where the memory device is a read only memory device. The availability of this information with or without the use of a database has the same beneficial effect in reducing abuse, illegal distribution and theft as does the above described embodiment of the present invention.

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Other features and advantages of the invention will become apparent to those skilled in the art from the following detailed description. be understood, however, that the detailed description specific examples, while indicating preferred embodiments of the present invention, are given by way of illustration and not limitation. Many changes and modifications within the scope of the present invention may be made without departing from the spirit thereof, and the invention includes all such modifications.

## Brief Description of the Drawings

The present invention will be described below with reference to the accompanying drawings, wherein: 35

Figure 1 illustrates a uniquely identifiable drug

delivery device according to the present invention, shown as a patch, upon which a bar code identifier is placed;

Figure 2 illustrates a uniquely identifiable drug delivery device according to the present invention, shown as a patch, upon which an alphanumeric string identifier is placed;

Figure 3 illustrates the information stored in a database for a particular drug delivery device; and

Figure 4 illustrates a uniquely identifiable drug delivery device according to the present invention, shown as a patch, within which a memory device is disposed.

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## Detailed Description of the Preferred Embodiments

reference described herein with accompanying drawings, the present invention provides a 20 method and system for identifying and tracing the ownership of an individual drug delivery device. allows authorities to investigate more effectively any illegal distribution or theft of drug delivery devices, devices containing controlled specifically those 25 It also has the effect of reducing abuse substances. and making available more of the supply of the controlled substance for use by legitimate users.

While the descriptions herein primarily refer to the identification of a patch for delivering a controlled substance such as MPH, it will be apparent to one skilled in the art that the invention has applicability to other drug delivery devices and drugs.

Accordingly, as used herein, the term "drug delivery device" shall further include aerosol canisters such as those used for inhalation therapy, pre-filled syringes,

IV bags, bottles, ampules, tamper-proof packaging and any unit-dose drug packaging.

The term "drug" as used herein is intended to have the broadest meaning and includes at least one of any 5 prophylactic, pharmacological therapeutic, physiological active substance, or mixture thereof, which is delivered to a mammal to produce a desired, usually beneficial, effect. More specifically, any agent which is capable of producing a pharmacological 10 response, localized or systemic, irrespective of whether therapeutic, diagnostic or prophylactic in nature, is within the contemplation for use with the invention. should be noted that the agents or drugs may be used singularly or as a mixture of two or more agents or 15 drugs, and in amounts sufficient to prevent, diagnose, mitigate or treat a disease or condition, as The invention has particular case may be. applicability for substances which have or can create an dependency habit-forming or addictive, 20 withdrawal symptoms upon cessation of usage. It is also applicable for use with substances which are or may be lethal, toxic or may cause serious adverse physiological effects if taken or administered in too great a dose or and hormonal anabolic steroids such as 25 substances such as testosterone and substances having a stimulant or depressant effect on the central nervous system.

In a first embodiment of the present invention, an 30 individual drug delivery device is encoded with a unique identifier, usually soon after its manufacture or as one of the final steps in its manufacture. The identifier allows a particular device to be differentiated from all Typical drug delivery devices facilitating such 35 coding are patches. As used herein the term "patch" device, any drug containing system, to refers

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composition, bandage, plaster, and the like, that is affixed to the skin or mucosa of a subject for systemic or local administration of the drug. Such devices for transdermal application are, for example, described in 4,994,267 and references such as U.S. Pat. Nos. 5,474,783, both assigned to Noven Pharmaceuticals, Inc., which are incorporated herein by reference. devices for transmucosal application are described in 5,446,070 assigned to No. Pat. U.S. Pharmaceuticals, Inc., which is incorporated herein by Such devices typically have a "backing" reference. which facilitates encoding by printing or labeling. Suitable materials that can be used, singularly, in combination, as laminates or as coextrusions, to form the backing are well known in the art and include films or sheets of polyethylene, polyester, polypropylene, polyurethane, polyolefin, polyvinyl alcohol, polyvinly polyvinylidene, polyamide, vinyl chloride, BAREX, ethylene/vinyl acetate resins, ethylene/ethylacrylate copolymers, metal-vapor deposited films or sheets thereof, rubber sheets or films, expanded synthetic resin sheets or foils and papers.

Various types of coding can be used under the Two examples are bar codes and present invention. 25 alphanumeric strings. Referring now to the drawings, it should be noted that the figures are illustrative in nature and are not drawn to scale. Figure 1 shows a patch 10 as the drug delivery device on which is placed a bar code 14 to uniquely identify the device. 30 code 14 can be printed on any area of the backing 12 of the patch 10. Figure 2 shows a patch 20 as the drug delivery device, similar to that of Figure 1, but where an alphanumeric string 24 is placed on backing 22 to uniquely identify the device. The alphanumeric string 35 24 can be a serial number or other string of characters of any length. By its nature, the alphanumeric string

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is more easily discernable by a person than is the bar code. Both types of codes, however, are readable by known electronic scanning devices. It is intended that other variations on the type of coding fall within the scope of this invention.

Preferably, the printing of a code is performed with waterproof, indelible ink such that the code cannot be removed without destroying the patch itself.

10 Alternatively, the coding can be incorporated into the drug-delivery device during production. For example, bar coding and alphanumeric strings can be printed on the underside of the backing layer 12 and 22 so that the coding cannot not be altered or removed by solvent. The patch would effectively have to be destroyed to tamper with the coding. Yet, the coding could be read through the backing layer 12 and 22.

According to the present invention, once a drug delivery device, such as a patch, has been encoded with an identifier, a corresponding identifier is placed into a database. While this can be accomplished at any time, placing an entry into a database corresponding to the actual device is preferably done by the manufacturer promptly upon manufacture of the device. The database itself preferably resides with the manufacturer but can In addition to the identifier, the be located anywhere. entry made into the database can include information as the name and quantity of the drug contained in the device, the date of manufacture, and the place of manufacture.

The device is then packaged for sale and distribution. Individually packaged patches can include an additional identifier on the packaging material itself. Furthermore, as multiple drug delivery devices are often packaged and distributed in sets, boxes

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containing such sets can be coded with an identifier representing and identifying the individually coded devices contained therein.

The present invention is not limited by the number of channels of distribution that may be in place with respect to any specific type of drug delivery device. Handlers of controlled substances must be licensed by the appropriate authorities, whether the handler is a bulk distributor of pharmaceutical products or a local When a particular device is transferred pharmacist. from one party to another, such as in a sale between two handlers, the identifier of the transferred device is recorded and the database is updated with information This recording of the pertaining to the transfer. device identifier, in the case of bar coding, can be done by an electronic scanning device. In the case of the recording can be done alphanumeric strings, The database is then electronically or by a person. updated with information such as the name of or code representing the identity of the transferee of the device, and the date of the transfer. In the case of multiple devices transferred in a prepackaged box, the identifier on the box is recorded. Upon transfer of the box identifier to the database, information pertaining 25 to all of the individual devices contained in the box Similar updates to the are updated accordingly. database are made whenever possession or ownership of an individual device is transferred. The recording of information and the updating of the database should be 30 accomplished at the time of transfer of possession.

Ultimately, when a drug prescription is filled by the last licensed handler for an end-user of the device, the information added to the database is, at minimum, the identity of the end-user to whom the device was Additional information added to transferred.

database can include the address of the patient, the RX#, the MD#, the identity of the prescribing physician, the DEA#, the pharmacy # and the date of dispensation or

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transfer.

sample set of the illustrates а 3 information stored in the database for a particular drug delivery device. The data set 30 all corresponds to the drug delivery device coded with individual "980704123456". This identifier identifier 31 represents the bar code symbol or is the alphanumeric string coded onto the actual device. The data set 30, shown in Figure 3, also contains the name and quantity of the drug contained in the device 32, "methylphenidate - 20mg". The manufacturer information 33, "ABC Manufacturing Co." is also included. The above describe data is usually entered into the database initially transferred is before the device Next, the first date of transfer 34 manufacturer. is the transferee is shown as "980720" Distribution Inc." A subsequent transfer to a pharmacy is shown by the second date of transfer 36 "980727" and the transferee 37 "Joe Pharmacist". Finally, the last recorded transfer is shown by the third date of transfer 38 "980803" and the transferee "Jane D. Patient" who presumably is the end-user.

find other authorities often Police and confiscate drug delivery devices containing controlled and unauthorized users substances from distributors. So long as the database has been updated, under the present invention, authorities have the ability to accurately identify and trace the ownership of a particular drug delivery device. Using the unique identifier on the individual drug delivery device, database and access the can authorities information regarding the device, such as the identities

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of: the person to whom the drug was dispensed, the pharmacy or other handler that dispensed the drug and any preceding handlers, such as distributors, of the device. Also, as discussed, the obtained information can include the date when the device came into the possession of each of the handling parties listed.

Using this information, authorities are better able to investigate and reduce the occurrence of illegal distribution or theft of the drug delivery devices, which, as discussed, can contain controlled substances such as MPH. For example, if the authorities were to confiscate from an unauthorized user the drug delivery device identified in Figure 3, based on the code found on the device and by accessing the database, they would know immediately that the device was known to be in the possession of Jane D. Patient on August 3, 1998. Such information would greatly assist in their investigation of the unauthorized sale or use of the controlled substance.

Furthermore, knowledge that such information is available to authorities will serve to diminish any inclination a handler may have to distribute the drug illegally. It will also encourage all handlers to take greater precautions against loss or theft or the drug delivery devices. An additional benefit of the present invention is that the reduction of abuse and illegal distribution of the controlled substance contained in the drug delivery device will make available more of the supply of the drug for use by legitimate users with a medical need.

In an alternate embodiment of the present invention, the above described method of tracking is implemented with drug-delivery devices that include a programmable microchip or a radio frequency

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identification (RFID) tag. In the case of a patch, a microchip or an RFID tag can be incorporated into the backing layer during production of the patch. Figure 4 illustrates a drug delivery device under the present invention, such as a patch 40, wherein a memory device 44, such as a microchip or RFID tag, is disposed within the backing layer 42. Alternatively, the programmable microchip or RFID tag is affixed onto the backing layer of the patch during later stages of the production process, before the device is pouched. Thin and flexible RFID tags are known in the art. Moskowitz et al., in U.S. Pat. No. 5,528,222, disclosed such an RFID tag having a semiconductor circuit with logic, memory, and a radio frequency circuit in a thin and flexible package for use with such items as credit cards, passports, admission tickets and postage stamps.

Under the present invention, there are certain advantages to using microchips or RFID tags in drug-delivery device over barcodes. For example, while a bar code indicates an identification number for a specific drug delivery device, a microchip or RFID tag allows for additional information to be stored with the drug-delivery device, such as a physician #, a vendor #, etc. Unlike barcodes, information can be read, with a microchip or RFID reader, from the microchip or RFID tag on the patch while the patch is applied to the skin of the user and without removal of clothing. Also, RFID and microchip readers tend to be less expensive than bar code scanners.

It is envisioned that various types of RFID tags will be used in accordance with the present invention. The use of passive RFID tags, those which rely on power from an external reader, is preferred. It is also possible, however, to use active RFID tags, those which contain their own power supplies, providing they are

sufficiently thin to be disposed on or in the drug delivery device. The various RFID tags contain differing memory capacities and operate in different frequency ranges. It will be apparent to one skilled in the art that the present invention is not limited by such factors.

It is intended that the invention, as described herein, include all variations and modifications as fall within the scope of the claims and equivalents thereof.

## What Is Claimed Is:

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1. A method of identifying and tracing the ownership of an individual drug delivery device, the method comprising:

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coding said individual drug delivery device with a code uniquely identifying the individual drug delivery device;

placing said code in a database; and adding information to said database corresponding to said code upon a transfer of possession of said device, wherein said information comprises at least one of the identity of a transferee in said transfer, the identity of a prescribing physician, the identity of a dispensing pharmacy, the date of said

- transfer, and the name and amount of a drug contained in said device.
- 2. A method according to claim 1, wherein the 20 coding of said device is in a form selected from the group consisting of a bar code, an alphanumeric string, a microchip and an RFID tag.
- 3. A method according to claim 2, further comprising:
  storing additional information in said one of a microchip and RFID tag, said additional information consisting essentially of at least one of the identity of a prescribing physician, the identity of a dispensing pharmacy and the date of said transfer.
  - 4. A method according to claim 1, wherein said code is readable by means of electronic and visual means.
  - 5. A method according to claim 1, wherein said drug delivery device is selected from the group

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consisting of aerosol canisters, pre-filled syringes, IV bags, bottles, ampules, tamper-proof packages, unit-dose packages, patches, and iontophoretic devices.

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- A method according to claim 1, wherein said 6. 5 drug delivery device is a patch which comprises a backing, and said code is printed code on a surface of said backing.
- A method according to claim 1, wherein said 10 drug is a controlled substance.
- A system for uniquely identifying and tracing ownership of a drug delivery device, said system comprising: 15

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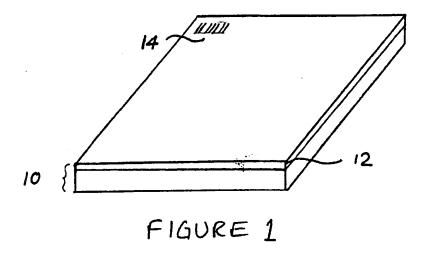
- an individually coded drug delivery device including
  - a carrier for containing a quantity of a drug;
- a code disposed on said carrier for uniquely identifying said individual device; and
- said code and for storing database information pertaining to said device upon a transfer of possession of said device, wherein said information comprises at least one of the identity of a transferee said transfer, the identity of a prescribing physician, the identity of a dispensing pharmacy, the date of said transfer, and the name and amount of a drug contained in said device.
- A system according to claim 8, wherein said 30 code is in a form selected from the group consisting of a bar code, an alphanumeric string, a microchip and an RFID tag.
- 10. A system according to claim 8, wherein said 35 code is readable by means of electronic and visual means.

11. A system according to claim 8, wherein said carrier is a patch which comprises a backing, and said code is printed code on a surface of said backing.

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12. A system according to claim 8, wherein said drug is a controlled substance.



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FIGURE 2

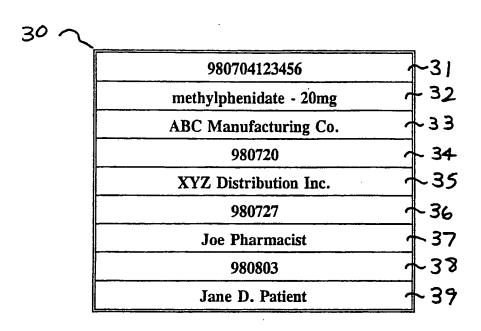


FIGURE 3

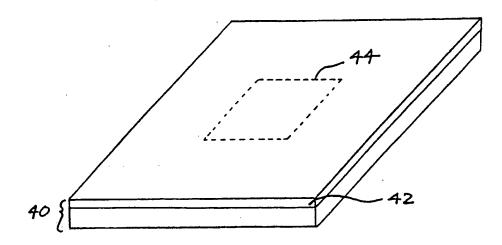


FIGURE 4

#### INTERNATIONAL SEARCH REPORT

Inter vial Application No PCT/US 99/16042

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 G06F19/00 G06K G06K19/00 G06F17/60 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) G06F G06K IPC 7 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. WO 98 28676 A (PYXIS CORP) 1,2,4-12 χ 2 July 1998 (1998-07-02) 3 Y page 1, line 10 -page 6, line 15 page 20, line 1 - line 15 Y US 5 448 110 A (TUTTLE ET AL) 3 5 September 1995 (1995-09-05) column 1, line 16 -column 3, line 14 column 6, line 12 -column 7, line 47; figure 1 1,2,4, WO 97 07473 A (PATIENT SOLUTIONS INC) X 8-10 27 February 1997 (1997-02-27) page 5, line 23 -page 11, line 12; figures Patent family members are ested in annex. Further documents are listed in the continuation of box C. 3 Special categories of cited documents : "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-"O" document referring to an oral disclosure, use, exhibition or ments, such combination being covious to a person skilled in the art. document published prior to the international filling date but later than the priority date claimed "&" document member of the same patent family Date of mailing of the international search report Date of the actual completion of the international search 04/11/1999 27 October 1999 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 European Facili Oince, F.B. 3010 Fateritial NL – 2280 HV Rijswijk Tel. (+31-70) 340–2040, Tx. 31 651 epo ni, Fax: (+31-70) 340–3016 Schenkels, P

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Inter: onal Application No
PCT/US 99/16042

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	ation) DOCUMENTS CONSIDERED TO BE RELEVANT  Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Category 3	Спанон от оосилени, with indication, where appropriate. От the research passages	
A	US 5 628 530 A (THORNTON GARY B) 13 May 1997 (1997-05-13) column 2, line 3 - line 63	1,8
<b>A</b>	US 4 953 745 A (ROWLETT JR JAMES R) 4 September 1990 (1990-09-04) abstract column 2, line 12 -column 3, line 6	1,8

1

## INTERNATIONAL SEARCH REPORT

Jornation on patent family members

Inter onal Application No PCT/US 99/16042

Patent document cited in search report	t	Publication date		atent family nember(s)	Publication date
WO 9828676	Α	02-07-1998	AU	5518198 A	17-07-1998
US 5448110	 А	05-09-1995	US	5779839 A	14-07-1998
			DE	4319878 A	23-12-1993
			JР	2857029 B	10-02-1999
			JP	6123773 A	06-05-1994
			US	5787174 A	28-07-1998
			US	5776278 A	07-07-1998
WO 9707473	Α	27-02-1997	US	5752234 A	12-05-1998
			AU	6850796 A	12-03-1997
US 5628530	Α	13-05-1997	NONE		
US 4953745	Α	04-09-1990	NONE		